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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,260	03/26/2004	Zhiwei Jiang	22596-537 CON	8306
30623 7590 07/27/2007 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER KOSACK, JOSEPH R	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 07/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/810,260	Applicant(s) JIANG ET AL.	
	Examiner Joseph Kosack	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Restriction Requirement mailed on September 23, 2005 has been modified.

Claims 1-65 are pending in the instant application.

Election/Restrictions

Applicant's election with traverse of Group V (claims 38-49 and 64) along with an election of species in the reply filed on March 16, 2007 is acknowledged. Applicant's arguments have been considered, but were not found to be persuasive as to the species requirement. The restriction requirement has been modified as described below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to compounds and compositions having compounds having the structure of formula I, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- II. Claims 6-10, drawn to methods of treatment using compounds having the structure of formula I, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- III. Claims 11-14, drawn to compounds and compositions having compounds having the structure of formula II, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.

- IV. Claims 15-19, drawn to methods of treatment using compounds having the structure of formula II, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- V. Claims 20-23, drawn to compounds and compositions having compounds having the structure of formula III, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- VI. Claims 24-28, drawn to methods of treatment using compounds having the structure of formula III, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- VII. Claims 29-32, drawn to compounds and compositions having compounds having the structure of formula IV, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- VIII. Claims 33-37, drawn to methods of treatment using compounds having the structure of formula IV, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- IX. Claims 38-44, drawn to compounds and compositions having compounds having the structure of formula V, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- X. Claims 45-49, drawn to methods of treatment using compounds having the structure of formula V, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.

- XI. Claims 50-51, drawn to a method of making compounds having the structure of formula I, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- XII. Claims 52-53, drawn to a method of making compounds having the structure of formula II, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- XIII. Claims 54-55, drawn to a method of making compounds having the structure of formula III, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- XIV. Claims 56-57, drawn to a method of making compounds having the structure of formula IV, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- XV. Claims 58-60, drawn to a second method of making compounds having the structure of formula I, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- XVI. Claims 61-63, drawn to a second method of making compounds having the structure of formula III, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.
- XVII. Claims 64-65, drawn to a method of making compounds having the structure of formula V, classified in various subclasses of class 514, 540, 544, 546, 548, and 549.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating cancer can use the product of invention III instead of the product of Invention I.

Inventions I and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention I can be made using the process of Invention XV instead of that of Invention XI.

Inventions I and XV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention I can be made using the process of Invention XI instead of that of Invention XV.

Inventions I-II, XI and XV are unrelated from Inventions II-X, XII-XIV and XVI-XVII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP

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§ 802.01 and § 806.06). In the instant case, the different inventions have different core structures (designs) and are not disclosed as capable of use together.

Inventions II, XI and XV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs, do not overlap in scope, and are not claimed as obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating cancer can use the product of invention I instead of the product of Invention III.

Inventions III and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case the process can be used to make compounds with a 5-membered sulfur ring instead of the product of Invention III.

Inventions IV and XII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs, do not overlap in scope, and are not claimed as obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III-IV and XII are unrelated from Inventions V-X, XIII-XIV and XVI-XVII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different core structures (designs) and are not disclosed as capable of use together.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process

of treating cancer can use the product of invention III instead of the product of Invention V.

Inventions V and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention I can be made using the process of Invention XVI instead of that of Invention XIII.

Inventions V and XVI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention I can be made using the process of Invention XIII instead of that of Invention XVI.

Inventions V-VI, XIII and XVI are unrelated from Inventions VII-X, XIV and XVII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different core structures (designs) and are not disclosed as capable of use together.

Inventions VI, XIII and XVI are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect;

(2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs, do not overlap in scope, and are not claimed as obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating cancer can use the product of invention I instead of the product of Invention VII.

Inventions VII and XIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make compounds with a 6-membered sulfur ring instead of the product of Invention VII.

Inventions VIII and XIV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs, do not overlap in scope, and are not claimed as obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions VII-VIII and XIV are unrelated from Inventions IX-X and XVII.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different core structures (designs) and are not disclosed as capable of use together.

Inventions IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating cancer can use the product of invention I instead of the product of Invention IX.

Inventions IX and XVII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process

(MPEP § 806.05(f)). In the instant case the process can be used to make compounds with a 5-membered sulfur/oxygen ring instead of the product of Invention IX.

Inventions X and XVII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different designs, do not overlap in scope, and are not claimed as obvious variants. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

As an additional requirement, with the election of one of the above groups, a provisional election of species of a particular compound is also required. Additionally, if Group II were elected a particular disease to be treated must also be elected. This election must include the compound name or structure, the location of the species

within the claims or the specification, and a delineation of the exact substitutions on the general Markush formula, e.g. R5 is hydrogen, X is oxygen, etc...

Examination will begin with the elected species. As per MPEP 803.02, if the elected species is found to be unpatentable, the provisional election will be given effect and all other claims to species will be withdrawn from consideration. If the elected species is found to be allowable, the search will be expanded by the Examiner to consider additional species and subgenres within the generic formula until:

- I. An art rejection can be made.
- II. The genus claim is found to lack unity of invention.
- III. The claims have been searched in their entirety.

Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

Advisory of Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

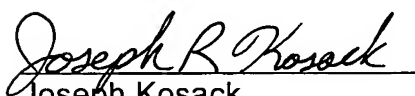
Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

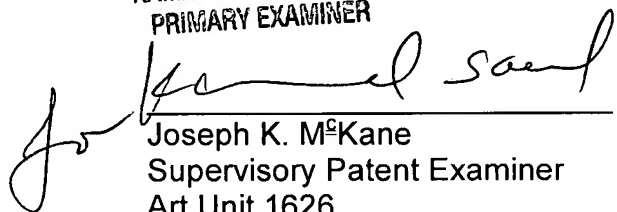
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Kosack whose telephone number is (571)-272-5575. The examiner can normally be reached on M-F 6:30 A.M. until 4:00 P.M. The examiner has every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^cKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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